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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,342	11/20/2001	Robert C. Simpson	13421.0002.NPUS00	5345

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Robert J. McAughan, Jr.
Howrey Simon Arnold & White, LLP
750 Bering Drive
Houston, TX 77057-2198

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/989,342

Applicant(s)

SIMPSON, ROBERT C.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-12,15-18,51-53 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-12,15-18,51-53 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/04 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: both (1) “the loading of the catheter into the epidural dispenser system is performed mechanically” in claim 17 and (2) “the loading of the catheter into the epidural dispenser system is performed through an automated process” in claim 18 are not included in the descriptive portion of the specification.

The abstract of the disclosure is objected to because: 37 CFR 1.72 states the abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 6 and 55 are objected to because of the following informalities: these claims are entirely functional and do not further limit the structure of the device as claimed and are only drawn to the use of the device. Due to the amount of functional language in these two claims, the examiner reminds applicant that functional language is given limited patentable weight. As long as a prior art reference, while meeting the structural limitations of the claimed device, is capable of accomplishing the recited function, then the claimed device does not overcome the cited prior art. Conversely, in a method claim more patentable weight is given to function language. In light of the preamble, the examiner is considering these claims to be apparatus claims and these claims have been given minimal patentable weight.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,6-8,10-12,15,51-53 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Pevsner (USPN 4,159,022). Regarding claims 1,11,15,52 and 56, Pevsner discloses a catheter delivery system that includes a delivery housing (21) with a single cavity (inside of 53) that has at least one cylindrical and conical sidewall (53) having a proximal end (at # 59) and a distal end (65), the distal end being connected to a distal end piece (67), thereby defining the single inner cavity. See figure 4. The distal end piece defines the upper border of

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the inner cavity. See figure 4. The distal end piece includes a dispensing aperture (aperture in 67) such that a loaded catheter (13) in the inner cavity can be extracted from the inner cavity through the dispensing aperture. See figure 1 and 3:60-4:6. The dispenser including the dispensing aperture is considered made of semi-rigid material. Even though Pevsner does not disclose the type of material the device is made from, all material has some degree of rigidity (depending on the reference point or value) and is therefore semi-rigid. The term semi-rigid is a relative term and without a reference point or reference value the term semi-rigid is a broad limitation that is met by any material.

Regarding claims 2,12,51 and 53, the sidewall (53) of the delivery housing (21) is attached to a proximal end piece (55) which further defines the inner cavity. See figure 1. The proximal end piece defines a loading aperture (hole in cap see 3:5) such that the catheter (13) may be loaded or adjusted into the inner cavity through the loading aperture. See figure 4 and 3:30-45.

Regarding claims 6 and 55, the dispenser is capable of being positioned in either hand of a user such that the distal end is directed toward the user's thumb and index finger so that the catheter contained within the inner cavity may be completely extracted through the dispensing aperture. Due to the amount of functional language in these two claims, the examiner reminds applicant that functional language is given limited patentable weight. As long as a prior art reference, while meeting the structural limitations of the claimed device, is capable of accomplishing the recited function, then the claimed device does not overcome the cited prior art.

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Regarding claims 10 and 57, the inner cavity of the delivery housing (21) entirely confines the portion of the catheter that will enter the patient during the procedure except the portion of the catheter that is already extending from the delivery housing into the catheterizing tube 11. See figure 1 and 3:45-4:5. It is noted that "entirely confines" is being read broadly in the sense that the delivery housing sidewall is a solid structure that entirely confines the portion of the catheter that is shown in figure 1 and the text cited above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner. Pevsner meets the claim limitations as described above but fails to include the sidewall taking the shape of a polyhedron.

At the time the invention was made, it would have been an obvious matter of design choice to make the sidewall of Pevsner polyhedral in shape. Applicant has not disclosed that having the sidewall polyhedral in shape serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Pevsner's delivery housing and applicant's invention to perform equally well with either a cylindrical or a polyhedral housing because either shape would perform the same function of entirely confining a portion of a catheter for insertion into a patient's body equally well considering either shape would provide a

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single inner cavity. Therefore, it would have been prima facie obvious to modify Pevsner to obtain the invention as specified in claim 9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Pevsner.

See also *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner. Pevsner meets the claim limitations as described above but fails to include the method steps of loading the catheter into the dispenser manually, mechanically or through an automated process.

Pevsner does disclose that the catheter is loaded into the dispenser through some type of loading process and outlines all the steps required to achieve a loaded catheter. See 3:30-60. Pevsner only fails to teach whether this process is manual, mechanical or automated. Pevsner also discloses that the catheter during the loading process is “forced, by hand, back through the mounting protrusion...” [emphasis added] See 3:55.

Therefore at the time of the invention, it would have been obvious to load the catheter manually since Pevsner already discloses a portion of the loading process being conducted manually.

Additionally, it would have been obvious to load the catheter through a mechanical or an automated process since the court has held that broadly providing an automatic or mechanical

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means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

Response to Arguments

Applicant's arguments with respect to claims 1-2,6-12,1518,51-53 and 55-57 have been considered but are moot in view of the new ground(s) of rejection.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams

January 5, 2005